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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/670,724 | 09/26/2003 | Kelvin G.M. Brockbank | 113024 | 6643 |

25944 7590 08/14/2006

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EXAMINER

SAUCIER, SANDRA E

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/670,724 | BROCKBANK ET AL. | |
| | Examiner | Art Unit | |
| | Sandra Saucier | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-20, 22-30, 32, 33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-20, 22-29, 32, 33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1–3, 7–20, 22–30, 32, 33, 35 are pending. Claims 1, 2, 7–20, 22–29, 32, 33, 35 are considered on the merits to the extent they read on the elected species, “cell culture” and “trehalose”. Claims 3 and 30 are withdrawn from consideration as being drawn to a non-elected species.

The delaration filed on 7/1⁴~~8~~/06 under 37 CFR 1.131 is sufficient to overcome the US 2005/0277107 reference.

Election/Restriction

This application contains claims 3 and 30 drawn to an invention nonelected with traverse in Paper No. 2/10/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections – 35 USC § 103

Claims 1, 2, 7–14, 17–20, 22–29, 32, 33, 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kim *et al.* [W].

The claims are directed to a method of preserving living cellular material comprising: incubating the material in a culture medium containing 0.1–0.4M trehalose for at least three hours and preserving. The elected species is cell culture.

Kim *et al.* disclose a method comprising incubating a cell culture of *T. chinensis* in a culture medium comprising 1M trehalose for 30 mins and freezing (Table 4). The reference lacks the incubation with trehalose for at least three hours.

It would have been obvious to incubate the cell culture for three hours or longer because an incubation of 30 minutes with trehalose is shown to increase viability. One of skill in the art may increase the incubation time in the absence of evidence of criticality. Further, the differences in the concentration of

trehalose is also considered to be an element of experimental design, particularly because 1M trehalose used in the prior art is in within the range of claim 26. See MPEP 2144.05.

Response to Arguments

Applicants argue that Kim *et al.* do not teach incubating the cellular material in a culture medium containing 0.1–0.4M trehalose, rather Kim et al teach addition of trehalose after freezing and thawing the cells. This is not persuasive because on page 47, Table 4, the cells prior to freezing were incubated on ice in cell culture medium containing 1M trehalose for 30 minutes, see legend and last data line and page 44, line 3 under ‘Cryopreservation’.

The length of incubation is considered to be well within the purview of one of skill in the art in the absence of evidence of criticality.

Claims 1, 2, 7–20, 22–29, 32, 33, 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,770,478 [A].

US 6,770,478 discloses a method of cell preservation where cells are incubated in a medium containing a concentration of trehalose in the loading (cryopreservation) medium from about 10mM to about 1.5M (col. 18, l. 60). The duration of the incubation is preferably about 4–24 hours (col. 19, l. 58). The internal concentration to be achieved is any suitable amount, preferably about 10mM–90mM trehalose (col. 19, l. 9). In examples 7–9, a method of incubating a cell in culture medium with 90mM trehalose for 24 hours. The cells are then harvested and resuspended in 150mM trehalose, frozen and dried.

Regarding claims 12–14, the duration of incubation is considered to be an element of experimental design in the absence of evidence of criticality. The reference teaches the preferable range of about 4–24 hours. However, one of skill in the art may choose any length of incubation time in the absence of criticality. Further, the use of a concentration range of 100–400mM is

considered to be obvious because the reference in the Summary of Invention teaches a non-limiting amount of oligosaccharide of which one is trehalose in the incubation medium and specifically exemplifies use of 90mM trehalose. Further since the broadest disclosure of the invention does not limit the disclosed invention of the specific oligosaccharide, trehalose, the use or addition of other oligosaccharides such as raffinose or sucrose to the incubation or loading medium are also considered to be obvious in the absence of evidence of criticality.

Response to Arguments

Applicant argue that US '478 teaches a preferred concentration of up to 50mM trehalose in the incubation medium. However, Examples 7 and 9 teach the use of 90mM trehalose in the incubation medium. In the broadest disclosures of the invention found in "Summary of the Invention", a non-limiting amount of oligosaccharide and preferably trehalose is loaded into the eukaryotic cells, col. 4, line 4. See MPEP 2123, "Disclosed examples and preferred embodiments do constitute a teaching away from a broader disclosures or nonpreferred embodiments."

Claims 28, 29, 32, 33, 35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burger *et al.* [X].

Burger *et al.* disclose a method of incubating cells in a culture media comprising 5% trehalose for 30, 60 and 90 mins., Tables 2 and 6 and Fig 9.

Burger *et al.* do not exemplify incubating for at least 3 hours.

Changes in duration of incubation are considered to be elements of experimental design in the absence of evidence to the contrary.

Response to Arguments

Applicants state that claims 28–35 have been cancelled, but this does not appear to be true from the listing of the pending claims.

Applicants argue that Burger *et al.* teach that incubation of the cells in the presence of trehalose does not increase the intracellular concentration from one hour to 90 minutes and therefore teaches that there is no benefit to incubating for more than one hour. However, applicants appear to be citing the data for galactose uptake. Please see Fig. 9 where trehalose is loaded into the cells. There may be a slight leveling off of the rate of intracellular loading from 60 to 90 minutes, but it appears that increasing the duration of trehalose incubation, in contrast to the loading of glucose, increases the intracellular concentration of trehalose. Thus, applicants' argument is not persuasive.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due

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to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'Sandra Saucier', with a large, stylized initial 'S' and a horizontal line extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
August 10, 2006